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WO 93/17640 A1 WO 87/06819 A1 US 5047063 A
US 4608054 A US 4536898 A

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(54) Apparatus for aligning a prosthesis

(57) Apparatus for fabricating a lower limb prosthesis and optimising the settings and angles associated therewith comprising; a socket for strapping to a residual limb having an end-cup onto which is bolted support-plate 23 which has an underlying anchor-block with four faces movable horizontally within alignment device 40 by adjusting four bolts in bores 47,49,(48,50). Alignment device 40 is angularly displaceable via a ball-joint with connecter 60 which also has an under-mounted tubular clamp holding a shin pylon which is releasably coupled to a prosthetic foot.

To fabricate a prosthetic device; 1) attach the above apparatus to a residual limb; 2) displace the anchor-block setting and ball-joint angle and fix; 3) walk-test alignment of the apparatus; 4) repeat steps 2-4 until alignment is optimal when the apparatus is laminated; 5) withdraw the apparatus from the newly formed prosthesis leaving the prosthetic foot coupling which remains incorporated in the fabricated device.

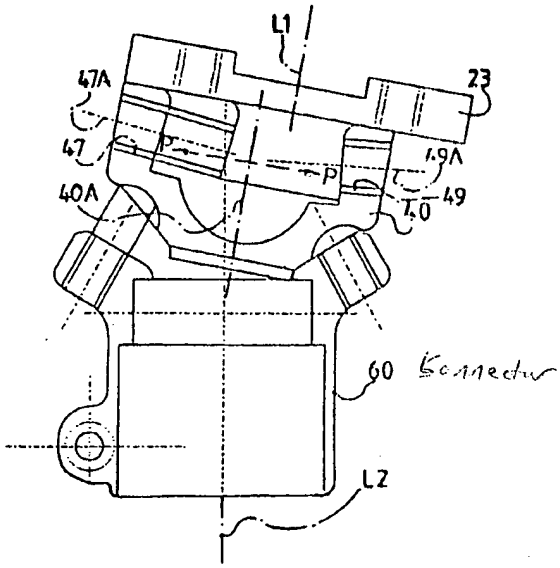


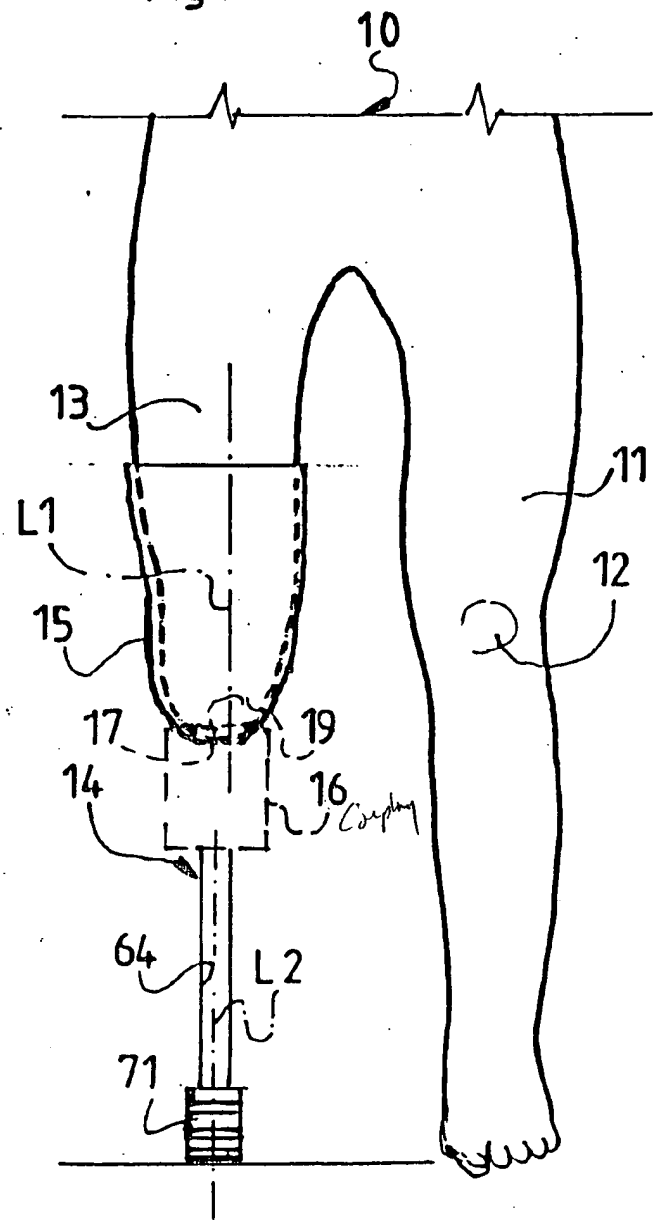
Fig 6A

GB 2 298 795 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

This print takes account of replacement documents submitted after the date of filing to enable the application to comply with the formal requirements of the Patents Rules 1990.

Fig1



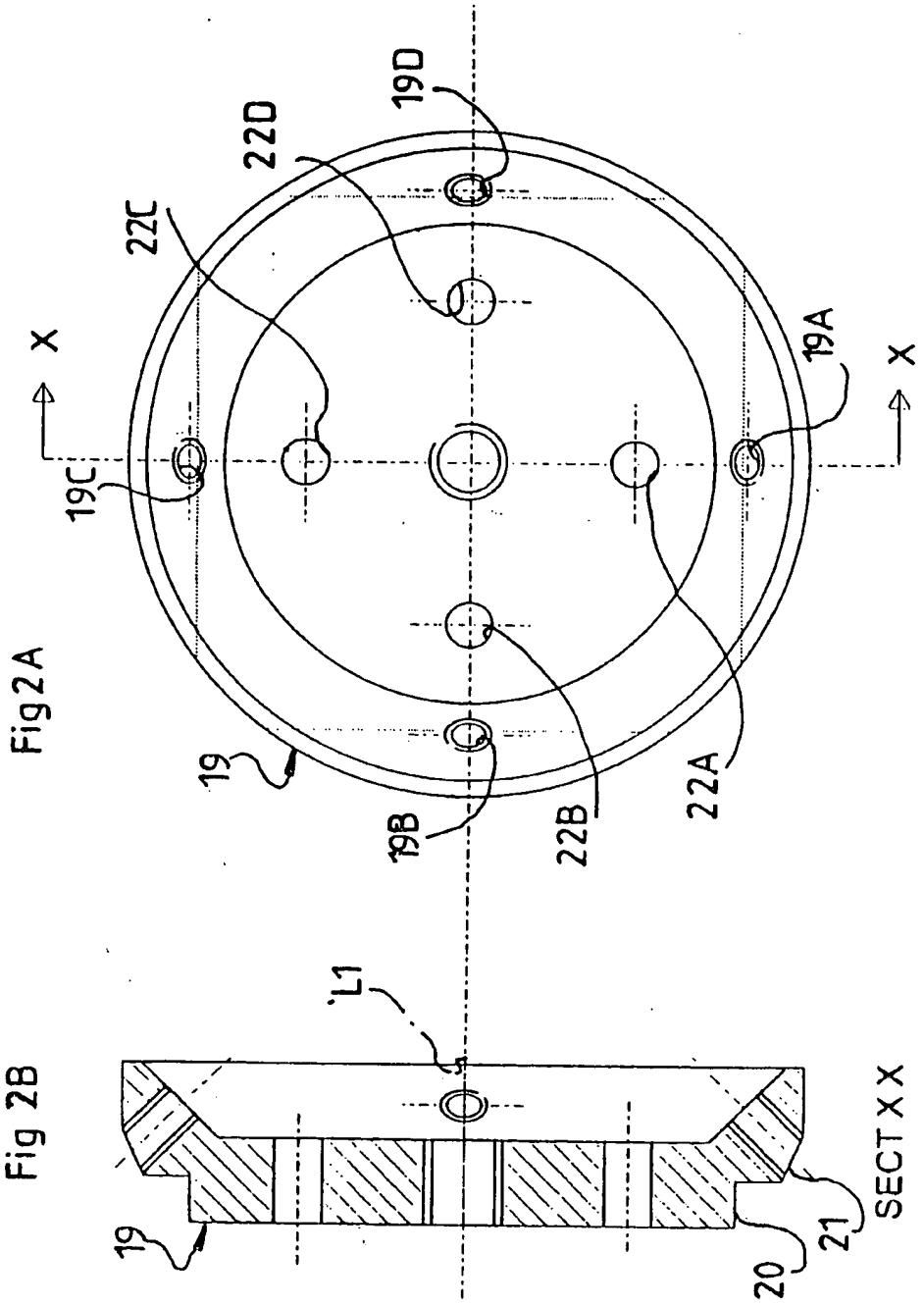


Fig 2A

Fig 2B

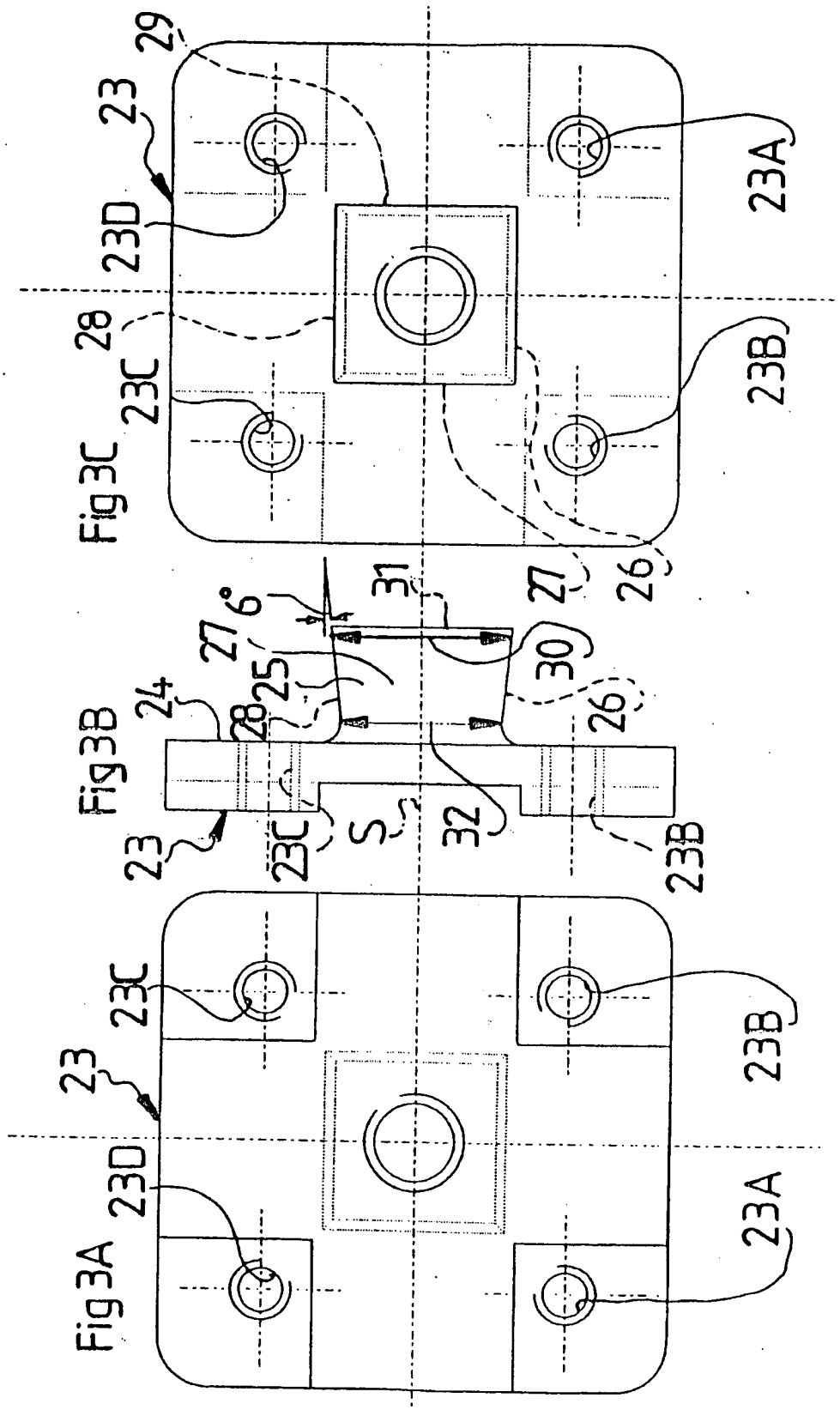
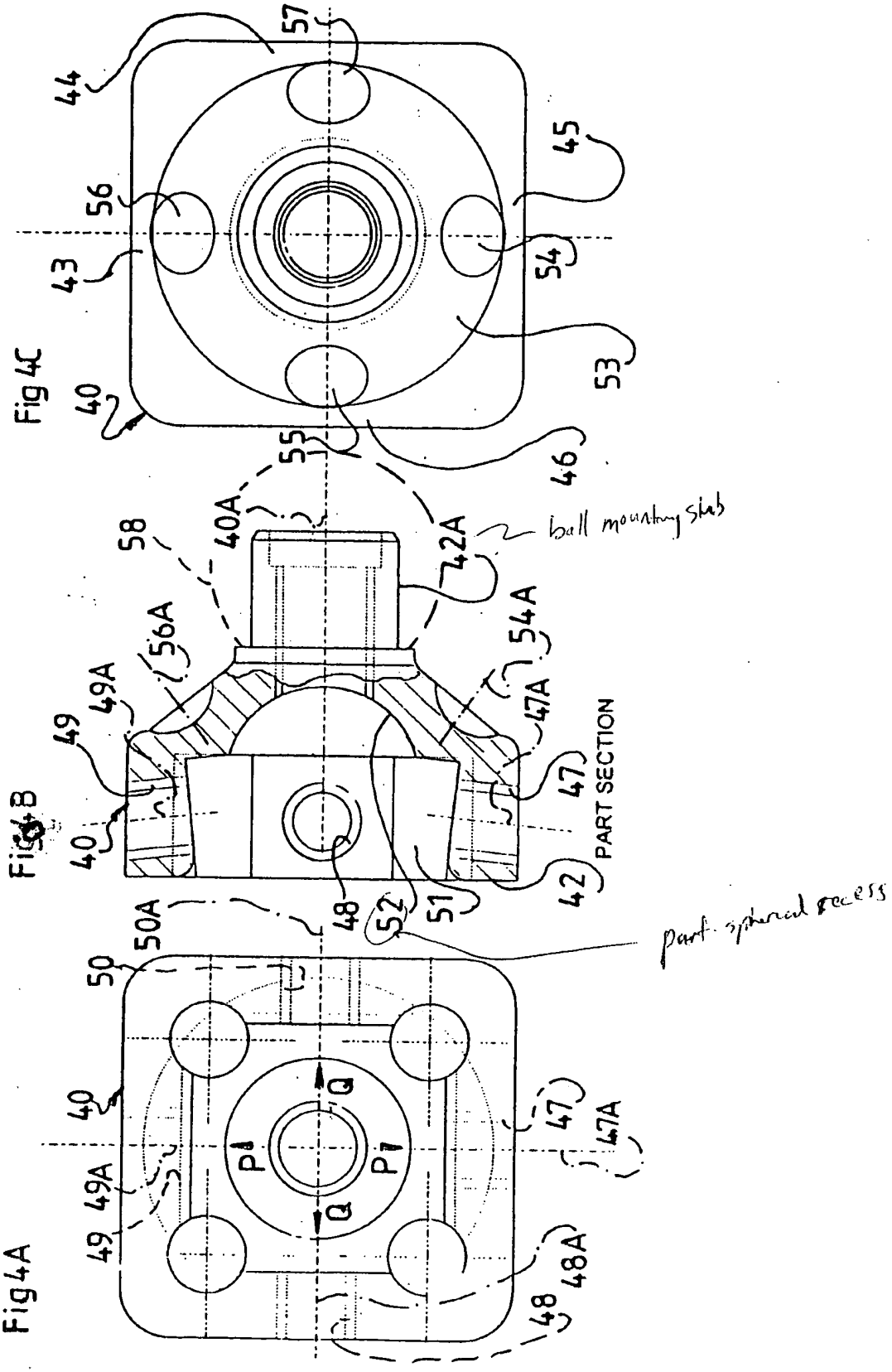


Fig 3C
29
23
23D
28
23C
23A
23B
26
27
31
6°
27
25
24
28
30
26
Fig 3B
23
23C
S
32
23B
Fig 3A
23C
23
23D
23B
23A


44
57
45
56
43
54
53
40
55
46
Fig 4C
58
40A
42A
ball mounting slab
56A
54A
49A
49
47A
47
PART SECTION
40
48
52
51
42
Fig 4B
50A
part spherical recess
50
40
Q
P
P
Q
47
47A
49A
49
48A
48
Fig 4A

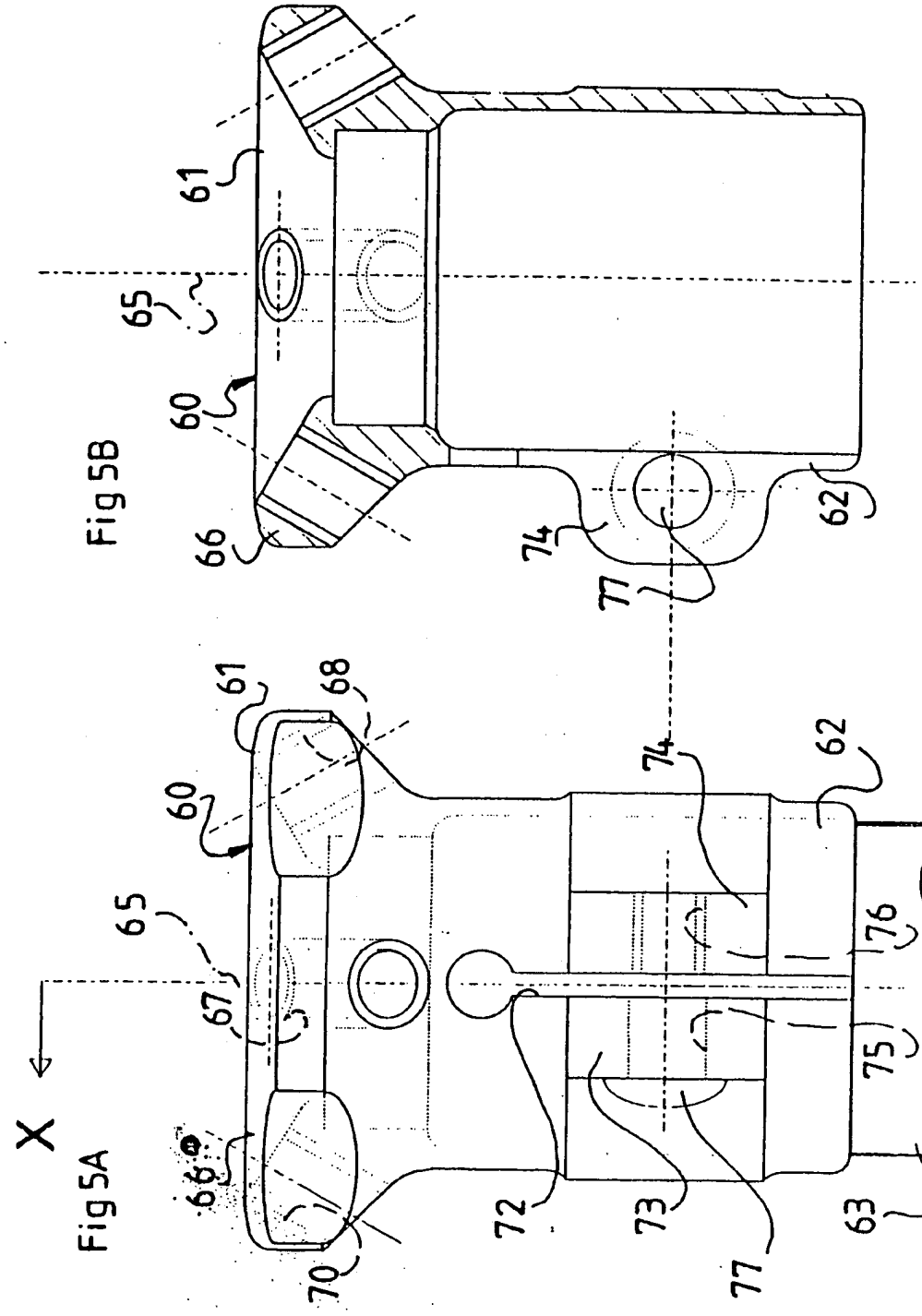


Fig 5B

Fig 5A

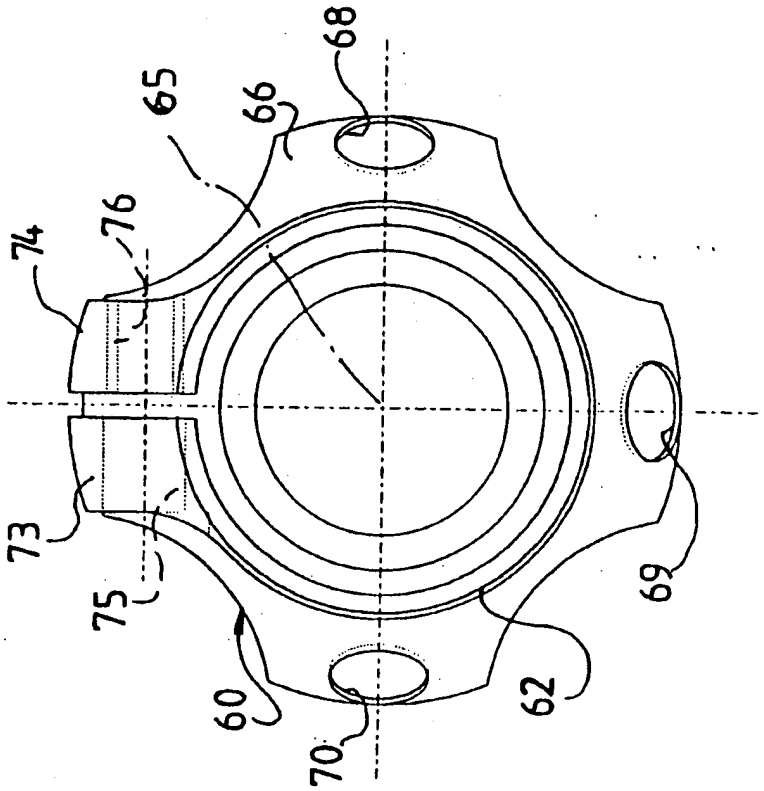


Fig 5C

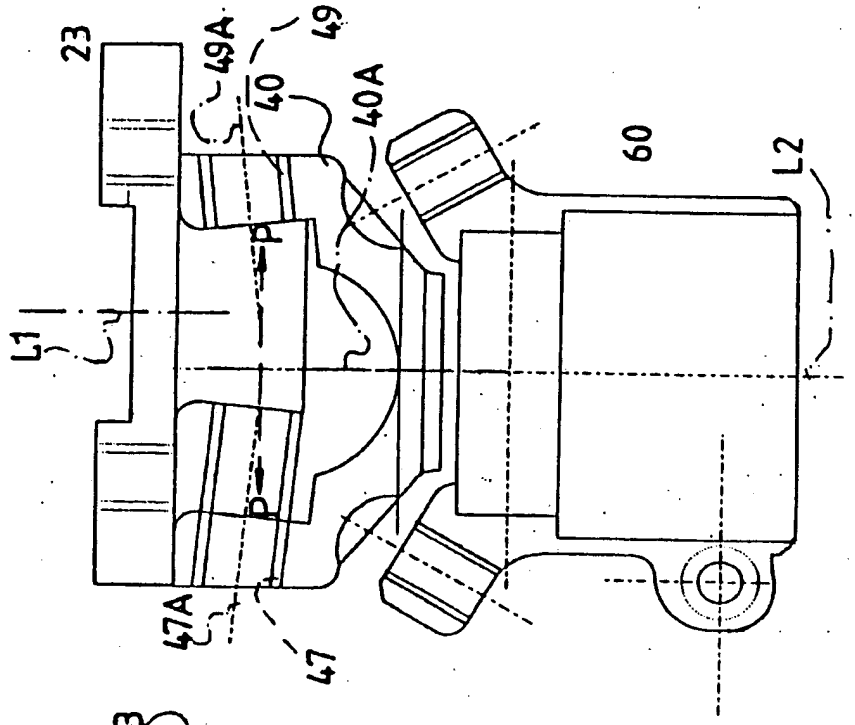

23
49A
49
40
40A
60
L2
L1
P
P
47A
47

Fig 6B

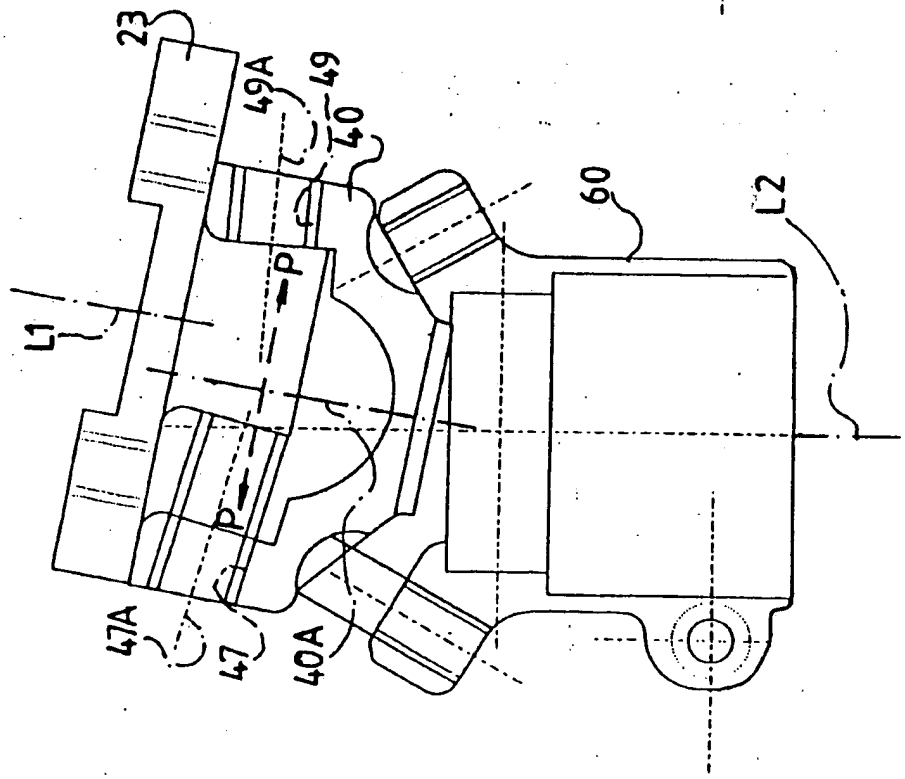

23
49A
49
40
60
L2
L1
P
P
47A
47
40A

Fig 6A

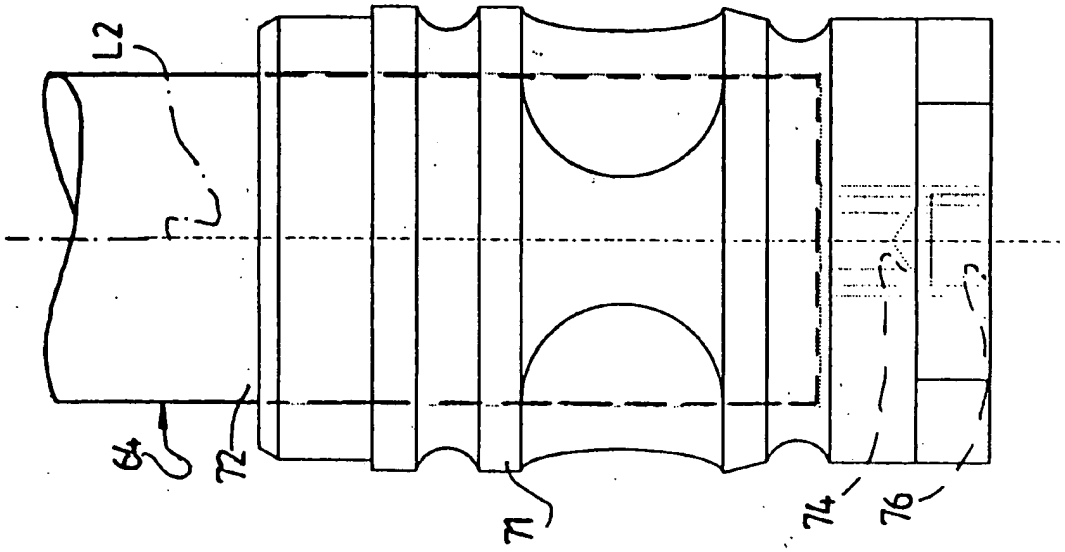


Fig 7A

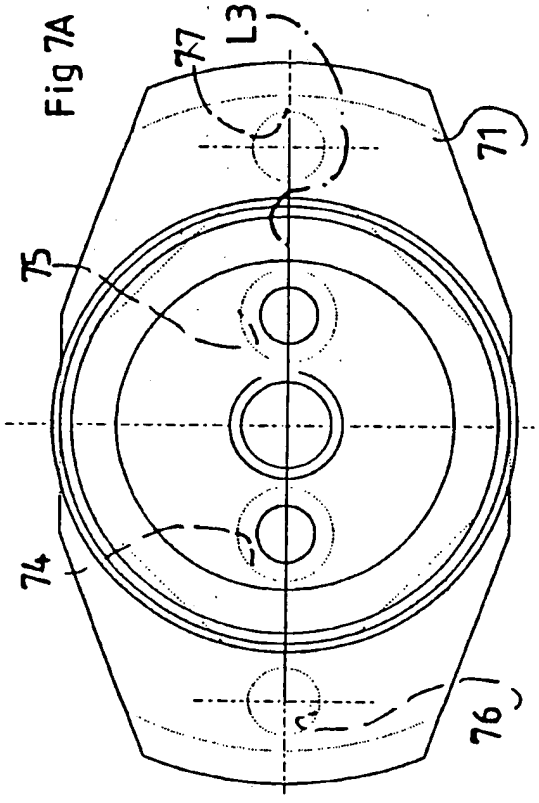
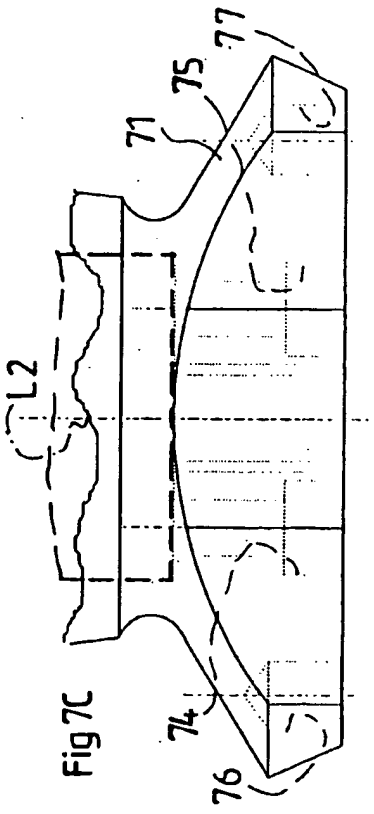


Fig 7C



ALIGNMENT APPARATUS AND METHOD

This invention relates to an alignment apparatus and method. In particular it is concerned with an alignment apparatus and method for use with an artificial limb.

For a person to be equipped with a prosthesis such as a lower leg it is important to provide accurate alignment between the existing leg stump and a foot artefact mounted on the prosthesis. Achieving this accurate alignment requires the services of a prosthetist.

To equip a user with a below knee prosthesis an accurately fitted socket is secured over the leg stump. From the lower end of the socket there extends a pylon and on the lower end of the pylon there is mounted a foot or other ground engaging member. Given that:

the stump has a first longitudinal axis,
the pylon has a second longitudinal axis;
the foot member has a ground contacting surface; and
the user has forward direction of travel defined by a third axis;

then there is a need to ensure that the prosthesis reproduces and optimal alignment of the first and second axis to enable the user to walk in the direction of the third axis during interaction of the foot member with the ground without causing undue reaction between the stump and the prosthetic device.

According to the a first aspect of the present invention there is provided alignment apparatus for a lower leg prosthesis comprising:

a socket for mounting on a residual limb of a user so as to provide a first longitudinal axis for a socket when mounted on the residual limb;
a pylon member having a first end and a second end; the first end being linked by a coupling to the socket; the second end providing for direct, or indirect, linkage to a ground engagable member; the pylon member having a second longitudinal axis;
the coupling between the socket and the pylon providing for:
angular adjustment of the first axis to the second axis;
clamping of the pylon in a given angular alignment of the first and the

second axis;

lateral displacement of the first axis relative to the second axis and clamping of the pylon in a given lateral alignment of the first and second axis.

According to a first preferred version of the first aspect of the present invention the coupling comprises:

a support plate for attachment to the socket; the support plate incorporating an anchor block having at least two horizontally opposed pairs of faces each lying in a plane which converges towards the socket;

an alignment device having:

at one end at least two horizontally opposed pairs of threaded members each pair being directed to correspondingly opposed faces on the anchor block to enable the alignment device to be either displaced relative to the support plate along a displacement axis transverse the first axis or to be secured in a selected position on the displacement axis;

a connector for the coupling to the pylon, the connector being linked to the alignment device by a ball joint to enable the pylon to either be angularly displaced relative to the socket or to be secured with a selected angle between the first axis and the second axis.

According to a second preferred version of the first aspect of the present or the first preferred version thereof the coupling incorporates a tubular clamp to receive and retain the pylon member.

According to a third preferred version of the present invention or any preceding preferred version thereof the pylon member is extensible to provide for overall length adjustment of the apparatus.

According to a fourth preferred version of the present invention or any preceding preferred version thereof the second end of the pylon is adapted to receive a foot or ground contacting member by way of a second coupling retained on the second end of the pylon by demountable means parallel to a longitudinal axis of the pylon.

Typically the second coupling provides for the foot or ground contacting member to rotate about an ankle axis perpendicular to the longitudinal axis of the pylon.

According to a second aspect of the present invention there is provided a method of fabricating a prosthetic device for a user having a residual limb comprising the steps of:

1 attaching an alignment apparatus as claimed in any preceding claim to a residual limb of a user;

2 providing a ground engaging member on the lower end of the pylon;

3 displacing the alignment device to a selected position on the displacement axis and thereafter retaining the alignment device in the selected position;

4 displacing the pylon relative to the socket to provide a selected angle between the first axis and the second axis and thereafter retaining the pylon in its selected position;

5 testing the alignment of the apparatus whilst secured to the user;

6 repeating one or both displacing steps as necessary to optimise the function of the secured apparatus, typically relative to the third axis; and

7 building-up the required prosthetic device on the apparatus so as to replicate the selected dimensions, positions and alignments.

According to a first preferred version of the second aspect of the present invention the building-up step involves lamination around the apparatus.

According to a second preferred version of the second aspect of the present invention or the first preferred version thereof wherein following the building-up step the apparatus is withdrawn from the fabricated device save for the second coupling which is left incorporated in the fabricated device.

An exemplary embodiment of the invention will now be described with reference to the accompanying drawing of an alignment apparatus for a below knee prosthesis of which:

Figure 1 is front elevation of part of a user equipped with the apparatus;
Figures 2A is a plan view, and
Figure 2B a section of a first component;

Figure 3A is a plan view from above,
Figure 3B is a side view, and
Figure 3C is a plan view from beneath of a second component;
Figure 4A is a plan view from above,
Figure 4B is a side view, and
Figure 4C is a plan view from beneath of a third component;
Figure 5A is a side view,
Figure 5B is a further side view at right angles to that of Figure 5A, and
Figure 5C is an end view seen from direction A in Figure 5A of a fourth component;
Figures 6A, 6B show the second, third and fourth components when assembled;
Figure 7A is a plan view from above,
Figure 7B is a side view, and
Figure 7C is a section on X-X of Figure 7A.

Figure 1

The lower part of a user 10 is shown with a complete left leg 11 with a knee joint 12. The user 10 has had their right leg amputated leaving a stump 13. In order to equip the user 11 with an artificial leg it is necessary to establish certain parameters in order to provide for the user 10 to be able to use an artificial leg to provide not only a stable standing stance but an ability to walk. The stump 13 has a longitudinal axis L1. To establish the necessary dimensions, angles and off-sets the alignment apparatus 14 is used by a prosthetist.

The stump 13 is clad with a socket 15 of fibre reinforced plastics material which is strapped to the body of the user 10 in a known manner. The interior of the socket 15 conforms closely to the configuration of the outside of the stump 13 from which it is separated by a sock of woven material.

The socket 15 is connected to the rest of the apparatus means generally indicated in Figure 1 as coupling 16. The socket 15 has anchored in aperture 17 in its lower end 18 a cup 19 (Figure 2) serving as an upper end for coupling 16. The apparatus 14 will

now be described with reference to Figures 2 to 7.

Figures 2A, 2B

Figure 2A shows the cup 19 in plan view and in Figure 2B in section. Cup 19 has a spigot 20 which projects through the aperture 17 and a chamfered perimeter 21 which closely abuts an inside complementary rim within the socket 15. The cup 19 is held in place in socket 15 by way of bolts extending through bores 19A-D. Bores 22A-D serve for the attachment of support plate 23 (Figure 3). Longitudinal axis L1 extends through axial centre of cup 19.

Figures 3A to 3C

Support plate 23 has projecting from its outer side 24 an integrally formed block 25 having four faces 26 to 29 laid out symmetrically in a square . The faces 26 to 29 are inclined inwardly at 6° so that length 30 of face 31 is greater than, typically, side 32 of the face 27. The support plate 23 is held in place on socket 15 by way of bolts extending through the bores 22A to 22D in the cup 19 engaging with, respectively, threaded bores 23A to 23D in the support plate 23. When support plate 23 is secured to cup 19 centre 23A is coaxial with axis L1.

Figures 6A, 6B show the relationship between support plate 23 and the remaining parts of the coupling 16 namely the alignment device 40 (Figure 4A to 4C) and connector 60 (Figure 5A and 5B).

Figures 4A to 4C

Alignment device 40 has a longitudinal axis 40A and comprises an end cup 42 and a ball joint mounting stub 42A.

The end cup 42 is square in plan with side walls 43 to 46 pierced by, respectively, threaded bores 47 to 50. The bores 47 to 50 have, respectively, longitudinal axis 47A to 50A. In use each bore 47 to 50 contains a bolt which can be displaced by being screwed along the axis of the bore either towards or away from the axis 41. Bores 47, 49 are in effect horizontally opposed in action and contain bolts by means of which the alignment device 40 can be displaced relative to the block 25 along axis PP. Likewise bores 48, 50 are effectively horizontally opposed and contain bolts by means of which block 25 can be displaced along axis QQ. By providing inclined faces 26 to 29 on the block 25 when all four bolts in bores 47 to 50 contact their associated block face the block 25 is retained in place relative to the alignment device 40.

Bores 47 to 50 open into an interior volume 51 with a part spherical recess 52 to enable block 25 to be readily displaced within volume 51, and thereafter readily secured, with a selected alignment between the support plate 23 and the alignment device 40 and so between axis S of support plate 23 and axis 40A of device 40..

End cup 42 has a frusto conical section 53 containing four depressions 54 to 57 laid out on a square pattern. Each depression 54 to 57 has, respectively, an axis of symmetry 54A to 57A whereby the end cup 42 is adjustably coupled to connector 60 as will be described hereafter.

Stub 43 extends symmetrically from cup 42 along axis 41 and serves to receive spherical bearing 58 which provides for ready angular displacement of the device 40 relative to connector 60 in which the bearing 58 is mounted as described hereafter.

Figures 5A to 5C

Connector 60 comprises a head 61 by means of which the connector 60 can be demountably secured to alignment device 40; and a skirt 62 whereby the connector is secured to upper end 63 of pylon 64. Longitudinal axis 65 of the connector is co-axial with longitudinal axis L2 of the pylon 64.

The head 61 has a recessed flange 66 lying at an angle of 60° to axis 65. The flange 66

has threaded bores 67 to 70 uniformly spaced around the flange 66. These bores 67 to 70 serve to receive bolts whereby the connector 60 can be linked to the alignment device 40. The inner ends of the bolts serve to seat in recesses 47 to 50 of device 40.

The skirt 62 contains a long keyhole slot 72. On either side of the slot 72 extensions 73, 74 contain coaxial bores 75, 76. Bolt 77 extending through bores 75, 76 allow for the circumference of the skirt 62 to be varied to provide for the clamping of the connector about pylon 64.

Figures 6A, 6B

These show the assembled components making up the coupling 16 with the components in two different relative positions.

Figure 6A shows alignment device 40 when locating block 25 at one extremity of travel along axis QQ when the face 27 of block 25 abuts the inner face of wall 44 of end cup 42. The block 25 can be displaced and located at any point along axis QQ over a range Q'. Likewise the block can be displaced and located at any point along axis PP (at right angles to axis QQ) and located at any point along axis PP over a range P'. In the chosen position for block 25 bolts in bores 47 to 50 of end cup 42 serve to clamp the block 25, and so the carrier 23 in a position in which the axis S, which is co-axial with axis L1 of the stump 13, is off set from axis 41 of device 40. In addition in the configuration shown in Figure 6A the axis S is at an angle to axis L2.

Figure 6B shows alignment device 40 with the block 25 as before abutting the inner face of wall 44 of end cup 42. However in this case the axis S is now off-set from axis L2 without being at an angle to it. Axis 41 of device 40 is in this case co-axial with axis L2.

By providing for block 25 to be readily off-set to a greater or lesser extent along axis PP or QQ or both the apparatus facilitates the ready setting of a working position for the apparatus which provided for independent angular and off-set displacement between axis L1 and L2.

Figure 7A, 7B and 7C

This shows a foot element 71 for attachment to lower end 72 of pylon 64 by way of sleeve 73. The element 71 serves to define an axis L3 for alignment with the direction of travel of the user 10. The element 71 is attached to pylon 64 by screws extending through bores 74, 75. Bores 76, 77 serve to attach a resilient sole to the foot element when required.

By providing a pylon of appropriate length to establish an overall length of the apparatus corresponding to that required for the leg length of the user 10 and making the necessary adjustments of alignment and off set to provide for the user 10 to stand and move in a stable manner a prosthetist having fitted the apparatus to the user can readily establish the optimum dimensions and angles required for a lower limb prosthesis for the user. After setting up and securing the apparatus with its components in the selected positions for the eventual user of the prosthetic device the socket 15 is removed from the residual limb complete with the alignment module attached with the established dimensions, angles and off-sets preserved.

A monolithic lower limb prosthesis is then built up by placing a preformed plastic former over the elements of the alignment module, following the removal of support plate 23, such that the former extends the length of the apparatus and with the upper end of the former abutting the lower periphery of socket 15 and the lower end of the former extending to the foot element 71. The prosthesis is then fabricated by a laminating process of lamination over the former.

Following lamination the cup 19 is removed to expose the upper end of the apparatus so as to allow the removal of the assembled coupling 16 and pylon 64. The socket 15, and foot attachment 71 are left incorporated as integral parts of the fabricated prosthesis for use by the patient. By providing bores 74, 75 in the foot attachment 71 which are parallel to axis L3 whereby screws attach the foot attachment to the pylon the pylon is readily released from the foot attachment 71 even when the attachment has been incorporated in the prosthesis built up on the assembled apparatus.

It will be apparent that the components of the recovered coupling 16 and pylon 64 are readily re-used in the production of a further prosthesis for another user.

The embodiment provides an alignment apparatus in the form of a set of components whereby a prosthetist can readily assemble, and locate the apparatus on a patient and thereafter establish the necessary parameters of lengths, angles and offsets on the suitably clamped up components of the apparatus. Once the apparatus is duly set up it is readily removed from the patient and the apparatus used directly in the fabrication of the prosthesis. It removes the need for taking off the parameters established during the trial and applying them as a separate step to components used in making up the eventual prosthesis. That is to say the apparatus once set up does not require a copying step but merely the creation of a prosthesis around the apparatus as assembled.

Moreover once the fabrication is completed the major part of the apparatus is readily removed from the fabrication and dismantled to provide apparatus elements for re-use.

CLAIMS

1 Alignment apparatus for a prosthesis comprising:
a socket for mounting on a residual limb of a user so as to provide a first longitudinal axis for a socket when mounted on the residual limb;
a pylon member having a first end and a second end; the first end being linked by a coupling to the socket; the second end providing for direct, or indirect, linkage to a ground engagable member; the pylon member having a second longitudinal axis;
the coupling between the socket and the pylon providing for:
angular adjustment of the first axis to the second axis;
clamping of the pylon in a given angular alignment of the first and the second axis;
lateral displacement of the first axis relative to the second axis and clamping of the pylon in a given lateral alignment of the first and second axis.

2 Alignment apparatus as claimed in Claim 1 wherein the coupling comprises:
a support plate for attachment to the socket; the support plate incorporating an anchor block having at least two horizontally opposed pairs of faces each lying in a plane which converges towards the socket;
an alignment device having:
at one end at least two horizontally opposed pairs of threaded members each pair being directed to correspondingly opposed faces on the anchor block to enable the alignment device to be either displaced relative to the support plate along a displacement axis transverse the first axis or to be secured in a selected position on the displacement axis;
a connector for the coupling to the pylon, the connector being linked to the alignment device by a ball joint to enable the pylon to either be angularly displaced relative to the socket or to be secured with a selected angle between the first axis and the second axis.

3 Alignment apparatus as claimed in any preceding claim wherein the coupling incorporates a tubular clamp to receive and retain the pylon member.

4 Alignment apparatus as claimed in any preceding claim wherein the pylon member is extensible to provide for overall length adjustment of the apparatus.

5 Alignment apparatus as claimed in any preceding claim wherein the second end of the pylon is adapted to receive a foot or ground contacting member by way of a second coupling retained on the second end of the pylon by demountable means parallel to a longitudinal axis of the pylon.

6 Alignment apparatus as claimed in Claim 5 wherein the second coupling provides for the foot or ground contacting member to rotate about an ankle axis perpendicular to the longitudinal axis of the pylon.

7 A method of fabricating a prosthetic device for a user having a residual limb comprising the steps of:

1 attaching an alignment apparatus as claimed in any preceding claim to a residual limb of a user;

2 providing a ground engaging member on the lower end of the pylon;

3 displacing the alignment device to a selected position on the displacement axis and thereafter retaining the alignment device in the selected position;

4 displacing the pylon relative to the socket to provide a selected angle between the first axis and the second axis and thereafter retaining the pylon in its selected position;

5 testing the alignment of the apparatus whilst secured to the user;

6 repeating one or both displacing steps as necessary to optimise the function of the secured apparatus, typically relative to the third axis; and

7 building-up the required prosthetic device on the apparatus so as to replicate the selected dimensions, positions and alignments.

8 A method of fabricating a prosthetic device as claimed in Claim 7 wherein the building-up step involves lamination around the apparatus.

9 A method of fabricating as claimed in Claim 7 or Claim 8 wherein following the building-up step the apparatus is withdrawn from the fabricated device save for the second coupling which remains incorporated in the fabricated device.

10 Alignment apparatus as hereinbefore described with reference to and as illustrated in Figures 1 to 7 of the accompanying drawings.

Patents Act 1977 Examiner's report to the Comptroller under Section 17 (The Search report)	Application number GB 9504862.5
Relevant Technical Fields (i) UK Cl (Ed.N) A5R RFA (ii) Int Cl (Ed.6) A61F 2/54, 2/58, 2/60, 2/64, 2/76	Search Examiner MR S J PILLING Date of completion of Search 22 JUNE 1995
Databases (see below) (i) UK Patent Office collections of GB, EP, WO and US patent specifications. (ii) NONE	Documents considered relevant following a search in respect of Claims :- 1 TO 10

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A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
X	GB 2149309 A	(BLATCHFORD & SONS) page 1 lines 6 to 8, page 3 lines 39 to 96 and Figure 9	1, 4
X	GB 1208421	(RUBERY, OWEN & CO) page 1 lines 37 to 57, page 2 lines 52 to 58 and Figure 6	1, 5, 6
X	EP 0267347 A1	(LANDSTINGENS INKOPSCENTRAL) column 1 lines 1 to 7, column 3 line 39 to column 4 line 36 and Figure 2	1, 3, 7, 8
X	WO 93/17640 A1	(PHILLIPS) page 2 lines 1 to 6, page 4 lines 1 to 24 and Figure 2	1, 3
X	WO 87/06819 A1	(RENNERFELT) page 1 lines 2 to 7, page 3 line 27 to page 4 line 4, page 5 lines 9 to 17, page 6 line 34 to page 7 line 8 and Figure 3	1, 3, 7, 8
X	US 5047063	(SEN-JUNG CHEN) column 1 line 46 to column 2 line 49 column 3 lines 27 to 31, column 4 lines 24 to 27 and Figure 5	1, 2, 3
X	US 4608054	(SCHRODER) column 1 lines 6 to 9, column 2 lines 10 to 31, column 5 lines 37 to 45 and Figure 4	1, 2
X	US 4526898	(PALFRAY) column 1 lines 24 to 42, column 2 lines 37 to 48, column 3 line 17 to column 4 line 34 and the Figures	1, 3

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